Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Effect of Noma Syrup (Lactuca sativa leaf extract) with Clonazepam Tablet on Insomnia Severity in Hemodialysis Patients

Protocol summary

Study aim
Determining the effect of Noma syrup (Lactuca sativa leaf extract) with clonazepam tablets on the severity of insomnia in hemodialysis patients.

Design
Clinical trial with control group, 102 patients were randomly assigned to two groups of 51 patients receiving Noma syrup and control (receiving clonazepam tablets) according to the computer program Permuted Block Randomization.

Settings and conduct
intervention group drink Noma syrup containing 240 ml every night for 20 ml, half an hour before bedtime for two weeks. The drug in the control group is clonazepam tablets, which will be given 0.5 mg of clonazepam tablets every night, half an hour before bedtime, for two weeks to the subjects in the control group. The severity of insomnia with the ISI index is completed before the start of the study and after two weeks of medication. The place of study is the Shahrvand center of Sari city.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People 18 years and older with insomnia problem, hemodialysis two or three times a week, Iranian nationality, mental alertness, ability to answer questions, no delirium, no cognitive problems, no history of stroke and Incurable diseases such as cancer, no severe hearing and vision problems and substance abuse. Exclusion criteria: Patients taking anti-anxiety or hypnotic drugs. Patients using accompanying therapies such as acupuncture, herbal remedies, hypnosis or yoga. The patient's unwillingness to continue the study, exacerbation of sleep disorders, delirium, allergic reaction or death of the patient are the exclusion criteria.

Intervention groups
In the intervention group, Noma syrup is consumed 20 ml every night, 30 minute before going to bed for two weeks. In the control group, clonazepam tablets will be given 0.5 mg of clonazepam tablets every night, 30 minute before bedtime, for two weeks.

Main outcome variables
Insomnia Severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110906007494N37**
Registration date: **2021-06-22, 1400/04/01**
Registration timing: **prospective**

Last update: **2021-06-22, 1400/04/01**
Update count: **0**

Registration date
2021-06-22, 1400/04/01

Registrant information

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Name of organization / entity
Mazandaran University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-01, 1400/04/10

Expected recruitment end date
2021-08-01, 1400/05/10

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Effect of Noma Syrup (Lactuca sativa leaf extract) with Clonazepam Tablet on Insomnia Severity in Hemodialysis Patients

Public title

The Effect of Noma syrup on insomnia in hemodialysis patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People 18 years and older with insomnia hemodialysis two or three times a week Iranian nationality mental alertness and ability to answer questions lack of delirium (Delirium Screening Nursing Scale (NE-DESC)) Lack Existence of cognitive problems (examination by MMSE test) no history of stroke Lack of incurable diseases such as cancer Absence of severe hearing and vision problems No substance abuse

Exclusion criteria:

Patients taking anti-anxiety or hypnotic drugs due to neuropsychiatric disorders Patients using combination therapies such as acupuncture, herbal remedies, hypnosis or yoga The patient's unwillingness to continue participating in the study Exacerbation of sleep disorder Delirium incidence Allergic reaction or death of the patient

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible individuals are randomly assigned to two groups of 51 intervention and control using random numbers provided by computer software and Permuted Block Randomization by a statistical consultant. 25 blocks of 4 and one block of 2 so that in blocks of 4, two people from the intervention group and two people from the control group and in the block of two, one person from the intervention group and one person from the control group . Therefore, 102 envelopes are designed and the letter A (intervention group) and the letter B (control group) are embedded in it based on the information obtained from the computer program. Envelopes are numbered from one to 102. Respectively, the first patient who is admitted to the ward and has the inclusion criteria enters the study after obtaining informed written consent and sampling continues until patient number 102.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square, Sari, Mazandaran, Iran.

City

Sari

Province

Mazandaran

Postal code

4816715793

Approval date

2021-06-13, 1400/03/23

Ethics committee reference number

IR.MAZUMS.REC.1400.245

Health conditions studied

1

Description of health condition studied

Insomnia severity

ICD-10 code

G47.00

ICD-10 code description

Insomnia, unspecified

Primary outcomes

1

Description

Insomnia Severity

Timepoint

Before the intervention and after the intervention

Method of measurement

Insomnia Intensity Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Noma syrup containing 240 ml of processed lettuce leaf extract is consumed 20 ml every night, half an hour before going to bed for two weeks.
Category
Treatment - Drugs

2

Description
Control group: Clonazepam tablets will be given half a mg each night, half an hour before bedtime, for two weeks to subjects in the control group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Specialized clinic of Shahrvand Kidney Patients Center
Full name of responsible person
Arash Azad Farzin
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Mazandaran University of Medical Sciences ,valiye asr highway, Joybar 3way ,Imam Sq,Sari, Mazandaran, Iran
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Sponsors / Funding sources

1

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Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more informatio
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available